

EXHIBIT H

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 Case No. 1:19-md-2875-RBK

4 _____)
IN RE: VALSARTAN, LOSARTAN AND)
5 IRBESARTAN PRODUCTS LIABILITY)
LITIGATION,)
6)
7)

THIS DOCUMENT RELATES TO ALL ACTIONS)
8)
9)

10 -----
DAY 2

11 CONFIDENTIAL

12 VIDEOTAPED DEPOSITION OF

13 DIPAK PANIGRAHY, M.D.

14 FRIDAY, SEPTEMBER 10, 2021

15 8:49 a.m. - 2:32 p.m.

16 GREENBERG TRAURIG LLP

17 ONE INTERNATIONAL PLACE, SUITE 2000

18 BOSTON, MASSACHUSETTS
19
20
21
22

23 Reported by: Sandra A. Deschaine, CSR, RPR,
24 CLR, CRA

25 Job No. 4769072

1 SEPTEMBER 10, 2021

2
3 8:49 a.m.

4
5 Videotaped Deposition of Dipak
6 Panigrahy, M.D., Day 2, held at Greenberg
7 Taurig, LLP, One International Place, Boston,
8 Massachusetts, pursuant to Notice, before
9 Sandra A. Deschaine, a Shorthand Reporter,
10 Registered Professional Reporter, Certified
11 LiveNote Reporter, and Notary Public in and
12 for the Commonwealth of Massachusetts.
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1 A P P E A R A N C E S:

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25 (Appearances continued.)

1 A P P E A R A N C E S (continued.)

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25 (Appearances continued.)

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1 follow up; and, like I said before, 10
2 different types of cancer were increased. So
3 what we do in science is we have to use a
4 whole set of papers, not rely on only one
5 paper.

11:07 AM

6 Q. Got it, Doctor.

7 In this case, in order for -- let
8 me start that again.

9 In this case, the NDMA detected in
10 the valsartan tablets would go to the liver
11 first, correct?

11:07 AM

12 A. So --

13 Q. Let me start the question again.

14 In this study, Doctor -- in this
15 litigation, Doctor, the exposure to the
16 levels of NDMA detected in the valsartan
17 tablets because of oral ingestion, would
18 first go -- first be metabolized by the
19 liver, correct?

11:07 AM

20 MR. NIGH: Form objection.

11:07 AM

21 A. Correct. There's a first-pass
22 metabolism initially.

23 BY MR. FOWLER:

24 Q. That's right, Doctor.

25 And the liver has the highest

11:08 AM

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1 humans likely have a higher bioavailability.

2 What that means is that the NDMA
3 can go past the first-pass metabolism in the
4 liver. And, in fact, we know that from the
5 occupational -- from the dietary studies,
6 that there's an increased risk of people who
7 had NDMA in their diet who took -- who had
8 NDMA exposed orally, had increased risk of
9 cancer.

11:09 AM

10 So we know in the gastric studies
11 I've documented in my report, with Song and
12 four other studies, there's statistical
13 increase, and in my report I detailed the
14 other types where the dietary studies, in
15 which the NDMA exposure is orally, have an
16 increased risk of cancer.

11:09 AM

11:10 AM

17 BY MR. FOWLER:

18 Q. Doctor, in order for NDMA to
19 escape the liver, it would have to not be
20 successfully metabolized through first-pass
21 metabolism, correct?

11:10 AM

22 Strike that. Ask it a different
23 way.

24 When NDMA is successfully
25 metabolized with first-pass metabolism, that

11:10 AM

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1 NDMA is excreted without going through the
2 rest of the body, correct?

3 MR. NIGH: Form objection.

4 A. Correct. If it's only first-pass
5 metabolism -- if a drug only goes through 11:10 AM
6 first metabolism, it won't make it to the
7 systemic. But what I'm saying is that we
8 know from the epi data that orally ingested
9 NDMA through the diet increased the risk of
10 multiple systemic cancers, and I've 11:10 AM
11 documented it in my report. It wasn't only
12 liver cancer. There's other cases where the
13 lung, the gastric -- yeah, in other systemic
14 cancers there's an increased risk. Even, for
15 example, esophageal and other types. 11:11 AM

16 BY MR. FOWLER:

17 Q. Doctor, there is a level of NDMA
18 that would be successfully metabolized with
19 first-pass metabolism; isn't that correct?

20 A. Correct. 11:11 AM

21 Q. That's what first-pass metabolism
22 means, right?

23 A. Correct.

24 Q. Tell the jury what what first-pass
25 metabolism means, sir. 11:11 AM

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1 throughout the body, and that's -- and that,
2 in conjunction with the Anderson 1991 paper,
3 where they gave NDMA to monkeys and showed in
4 32 different tissues that these adducts were
5 expressed; that that was because these
6 cytochrome P450s are expressed throughout the
7 body; while liver is the highest expression,
8 they're expressed everywhere.

11:15 AM

9 Q. Doctor, in order for the NDMA to
10 get to any other system in the body, it would
11 have to escape the liver.

11:15 AM

12 Can we agree on that?

13 MR. NIGH: Form objection.

14 A. Correct. To go -- systemically.

15 BY MR. FOWLER:

11:15 AM

16 Q. It would have to escape the liver
17 in order to reach any of those other organs
18 that you're talking about; correct?

19 A. Yes.

20 Q. And NDMA itself is fairly stable
21 without being metabolized, correct?

11:15 AM

22 MR. NIGH: Form objection.

23 BY MR. FOWLER:

24 Q. Withdrawn.

25 Doctor, you have no data in your

11:15 AM

SIGNATURE PAGE

DAY 2

IN RE: VALSARTAN, LOSARTAN AND IRBESARTAN
DIPAK PANIGRAHY, M.D. - SEPTEMBER 10, 2021

I, the undersigned, declare under penalty
of perjury that I have read the foregoing
transcript, and I have made any corrections,
additions or deletions that I was desirous of
making; that the foregoing is a true and
correct transcript of my testimony contained
therein.

Executed this _____ day of

_____ ,

at _____ , _____ .

(CITY)

(STATE)

DIPAK PANIGRAHY, M.D.